

JUN 21 2005

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Rajagopalan et al.
Serial No.: 09/898,887
Filed: July 31, 2001
Group Art Unit: 1653
Confirmation No: 2188
Examiner: Lukton
Title: **AROMATIC SULFENATES FOR TYPE I PHOTOTHERAPY**
Our Ref. No.: MRD-61

Cincinnati, Ohio 45202

June 14, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF RAGHAVAN RAJAGOPALAN
PURSUANT TO 37 C.F.R. §1.132

I, RAGHAVAN RAJAGOPALAN, declare as follows:

1. I am a named inventor in the above-identified patent application.
2. I hold a Ph.D. in Organic Chemistry from Columbia University. I have 21 years of experience in the synthesis and use of compounds for medical diagnosis and therapy, which is the subject of the application. I have read the outstanding August 25, 2004 Office action and May 12, 2005 Communication, and understand the position of the Examiner.

-Page 1 of 2 -

3. The specification at page 19, lines 11-13 discloses that a photosensitizer can be directly illuminated if a lesion is on a skin surface. This is applicable if the lesion is on a photo-accessible surface other than skin, such as a mucosal surface of the oral cavity, vagina, or nasal cavity. The specification also discloses that a photosensitizer can be illuminated using an endoscopic catheter equipped with a light source. Such an application may be used, for example, with a lesion in a blood vessel, lung, heart, throat, ear, rectum, bladder, stomach, intestines, or esophagus.

4. For at least the above reasons, it is my opinion that the claimed invention is fully enabled.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the subject application or any patent issued thereon.

June 21, 2005

Date

Raghavan Rajagopalan
Raghavan Rajagopalan, Ph.D.

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DECLARATION OF RICHARD DORSHOW
PURSUANT TO 37 C.F.R. §1.132

I, RICHARD DORSHOW, declare as follows:

1. I am a named inventor in the above-identified patent application.
2. I hold a Ph.D. in Physics from the University of California, Santa Barbara. I have 12 years of experience in the field of biomedical optics, and particularly, in the use of compounds for medical diagnosis and therapy, which is the subject of the application. I have read the outstanding August 25, 2004 Office Action and May 12, 2005 Communication, and understand the position of the Examiner.

-Page 1 of 2 -

3. For a lesion in an organ, such as liver, brain, prostate, breast, pancreas, etc., a photosensitizer in the tissue can be illuminated using a surgical instrument (forceps, scalpel, etc.) containing or configured with an illumination system. Such instruments are known to one skilled in the art, such as fiber optic instruments available from BioSpec (Moscow, Russia) for example, TC-I fiber optic tool for photodynamic therapy with fine needle tip for irradiating interstitial tumors (two pages attached and shown at [www.biospec.ru/ Fiber Optics e.html](http://www.biospec.ru/Fiber_Optics_e.html)). A surgeon performing a procedure is thus able to expose a tumor or other target tissue to light of a desired wavelength, power, and fluence rate during a procedure.

4. For at least the above reasons, it is my opinion that the claimed invention is fully enabled.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the subject application or any patent issued thereon.

June 14, 2005
Date

Richard Dorshow
Richard Dorshow

-Page 2 of 2 -



Fiber Optics

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In PDT, the light energy is delivered to the treatment site by means of a flexible fiber optic mostly. BioSpec offers medical laser delivery systems for [LPH](#) and [LESA](#) series of equipment.

These fibers have an outer diameter compatible with the working channels of the majority of endoscopes. A range of different light diffusing tips is available, especially designed for the type or size of tumor or tissue to be treated.

PDT Diffusers

TC-C5/10/20/40

Fiber optic tool for photodynamic therapy with 5/10/20/40 mm length cylindrical diffuser for intracavity tumors irradiating

TC-S

Fiber optic tool for photodynamic therapy with spherical diffuser for intracavity tumors irradiating

TC-D

Fiber optic tool for photodynamic therapy with direct irradiation for intracavity and superficial tumors

TC-A

Fiber optic tool for photodynamic therapy with angle diffuser for intracavity and superficial tumors Irradiating

TC-L

Fiber optic tool for photodynamic therapy with lens for superficial tumors Irradiating

TC-I

Fiber optic tool for photodynamic therapy with fine needle tip for interstitial tumors Irradiating



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LESA Probes

DC-R-1-6

Fiber optics probe for reflection and fluorescence measurements with LESAs



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